



PAIN MANAGEMENT
INSTITUTE

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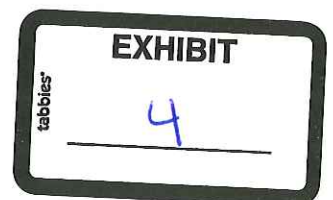
Expert Report by Thomas M. Larkin, M.D.

1. Background & Qualifications:

I am an anesthesiologist and interventional pain management specialist, licensed as a physician in Maryland, Pennsylvania, West Virginia and the District of Columbia. I obtained my undergraduate degree from State University of New York at Binghamton in 1986. I then obtained my medical degree from State University of New York, Health Science Center at Syracuse in 1991. From 1991 to 1992, I completed an internship at the Walter Reed Army Medical Center. I then completed a residency in anesthesiology in 1997, as well as a fellowship in pain management in 2000 at Walter Reed Army Medical Center.

I am board certified by the National Board of Medical Examiners and the American Board of Anesthesiology, where my score was in the 98th percentile on the written examination. I am also board certified by the American Board of Anesthesiology with added qualifications in Pain Management. I am a Diplomate in all of the above mentioned board certifications.

From 1992 to 1993, I was Brigade Surgeon for the 10th DIVARTY, 10th Mountain Division at Fort Drum, New York. From 1993 to 1994 as a Captain in the U.S. Army and acted as Joint Task Force Brigade Surgeon for the 10th JFT Brigade in Mogadishu, Somalia, as well as Acting Division Surgeon for the 10th Mountain Division at Fort Drum in New York. During that time frame, I also served as the Brigade Flight Surgeon for the 10th Aviation Brigade with the 10th Mountain Division at Fort Drum and Mogadishu for nine months.



From 1997 to 1999, I served as Coordinator for Continuing Medical Education for the Anesthesiology department. As an Assistant Professor of Anesthesiology at the Uniformed Services University of Health from 1997 through today I have taught residents and medical students at the nation's only military medical school. I have also served in a clinical capacity during this time as Attending Anesthesiologist with the Anesthesiology Department at Walter Reed Army Medical Center in Washington, DC and Bethesda, MD from 1997 to 2014.

In June of 2000 I participated as a Member of the United States Department of Defense and Veterans Administration Committee on Pain Management Guidelines. I served as Chairman for the Walter Reed Army Medical Center Process Action Committee on Pain Management from July of 2000 through June 2002. I also served as Medical Director was the Walter Reed Anesthesia Pain Clinic at the Walter Reed Army Medical Center from July 2000 through July 2003.

In September of 2002 I acted as the Medical Director for Pain Services and Pain Clinic at Landstuhl Regional Medical Center where I opened the first full service pain clinic in the European Regional Medical Command. I also served at the Attending Anesthesiologist at Landstuhl Regional Medical Center during this time.

From 2003 to 2005, I worked as Chief of Pain Management Services at Walter Reed Army Medical Center. My responsibilities as the Chief of that pain center included, but were not limited to, the support of the Regional Anesthesia and Pain Management initiative, inpatient and outpatient pain management support for Walter Reed Army Medical Center, primary instructor for the fellows in pain management regarding interventional pain management procedures, and advising the Surgeon General on issues specific to pain management support for the Army. I have also served as Assistant Chief and Acting Chief of Anesthesia and Operative Service at

Walter Reed.

In June of 2005 I began to work as a Staff Pain Physician with The Pain Management Institute in Bethesda, Maryland. I also began to work as a Staff Anesthesiologist and Pain Physician in a contractor role at Walter Reed in August of 2005.

From 2007 to 2015 I also served as Chief of the Pain Management Division at Parkway Neuroscience and Spine Institute, which is a multi-specialty practice comprised of pain management physicians, specializing in the care of spinal, pain and neurologic conditions. From May 2013 to May 2015 I acted as Managing Partner and President for this group responsible for overseeing the management, growth and operations of the largest neurosurgical and pain management practice in the region.

Finally, since January of 2016, I have been Owner and Co-President of The Pain Management Institute in Bethesda, Maryland, where I also serve as an anesthesiologist and pain management physician evaluating patients and performing pain procedures in a clinical setting. As Owner and Co-President of The Pain Management Institute I also collaborate with area physicians for the optimum care of the pain patients.

I am a member of the International Spinal Injection Society, the American Society of Interventional Pain Practitioners, the American Society of Anesthesiologists, the American Medical Association, the World Institute of Pain, and the North American Neuromodulation Society. I have published and presented in the areas including, but not limited to, anesthesiology, pain diagnosis, pain management, and pain treatment.

A copy of my *curriculum vitae*, more fully setting forth my experience and professional accomplishments, is attached as Exhibit 1. Any publications I have authored in the previous 10 years are listed on my *curriculum vitae*.

2. List of Cases

I have testified as an expert witness either in deposition or at trial within the past four years in the following cases:

Rhiannon Lloyd vs. James Bressi, DO, 2012, Summit County, OH, Case CV11-02-0816

Deigelman vs. Clifford Goldman, 2014, Firm: Eccleston and Wolff, PC Case 03-C-12-003749 MM

3. Facts and Data Considered in Forming My Opinions:

In forming my opinions, I have generally relied on my education, training, experience, and the materials I have reviewed. The following is a brief summary of the facts I rely upon in forming my opinions regarding Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., LLC, Ritu T. Bhambhani, M.D., LLC (collectively, "Box Hill Defendants" or "Box Hill"), and any agents or employees of the same.

a. Background for Dr. Bhambhani and Box Hill Surgery Center

Dr. Bhambhani is board certified in anesthesiology and pain medicine. In short, she graduated from medical school in 1994, and then did her post graduate training, including a residency and fellowship in anesthesiology and pain medicine, at the Cleveland Clinic in Ohio. She then obtained her Maryland license and began practicing anesthesiology and pain medicine in Maryland in 2000. She joined Harford County Ambulatory Surgery Center (in Maryland) in 2003, before opening Box Hill Surgery Center in 2008. Box Hill Surgery Center is a standalone ambulatory surgery center in Abingdon, Harford County, Maryland. Dr. Bhambhani is the sole owner and only regular physician at Box Hill, where she is also the Medical Director. Throughout the years, Dr. Bhambhani has practiced anesthesiology and pain medicine and has

Exhibit 2

- FDA Form 483 to NECC
- FDA Form 483 to ARL
- Massachusetts BOP/DPH Preliminary Investigative Report
- Report from the Massachusetts Board of Pharmacy's May 2011 inspection of NECC
- NECC Indictment
- Congressional Memo: "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"
- NECC Environmental Monitoring Results
- NECC Cleaning Logs
- NECC Standard Operating Procedures
- Liberty clean room punch list (Ex. 1202)
- Logged Formula Worksheets for the Three Contaminated Lots of MPA
- Daily Fill Logs for the Recalled Lots of MPA
- ARL Testing Results for Three Recalled Lots of MPA
- Video from NECC's Surveillance Cameras
- Video from Inspections of NECC's Facility in December 2012 and July 2014
- Disks containing audio from Barry Cadden's Training for Sales Personnel
- Floorplan Showing the Layout of NECC's Facility
- Scientific Air Analysis Testing Results from 2011 and 2012
- Monthly Cleaning Logs Completed by UniClean Technicians
- Documents regarding a 2012 complaint to NECC from Massachusetts Ear and Eye Institute (the customer complaint)
- Joe Cabaleiro, RPH, New England Compounding Center Indictment, Int' J. Phar Compounding, March- April 2015, at 94.
- ASHP Guidelines (Ex. 1327)
- NECC Quality Assurance Report Cards for 2011 and 2012
- Notes from Keith St. John and Ian Wallis from conversations with NECC's Joe Connolly
- Drug Recall Charts
- NECC Customer List
- FDA Warning Letter to NECC-12/06 (Ex. 1309)
- NECC Letter (1/5/07) to FDA in Response to FDA 2006 Warning Letter (Ex. 1310)
- FDA Letter (10/31/08) to NECC in Response to NECC Response Letter (1/5/07) to FDA 2006 Warning Letter (Ex. 1311)
- FDA Email (7/17/12) Regarding Colorado Cease and Desist Order (5/10/11) and FDA Not Taking Further Action Against NECC at this time (Ex. 1312)
- Emails between NECC and UniClean (Deposition exhibits 422, 424, 426-431)
- Photographs of NECC's standing autoclave
- Photographs of the gaps in ceiling of cleanroom 1
- PCCA formula for compounding MPA
- NECC advertising materials provided to some customers
- New York Times article reporting on several Johnson & Johnson product recalls

- US Compounding, Inc. voluntary recall; 2014-2015 FDA inspections of US Compounding, Inc.; 2012 and 2015 US Compounding, Inc. website printouts
- USP 797
- USP 71
- USP 85
- Expert Report/Declaration of Dr. Philip Austin, Ph.D.
- Deposition of Philip Austin, Ph.D.
- Deposition/Report of Keith St. John
- Deposition/Report of Ian Wallis
- Deposition/Report of Ray Schneider
- Deposition/Report of Sheldon Bradshaw
- Deposition/Reports of Brian Reisetter
- Deposition of William Mixon
- Deposition/Report of Robert Guardino
- Deposition of Stephen O'Neill
- Deposition of Francis McAteer
- Deposition of Michael Cotugno
- Deposition of Edwin Cardona
- Deposition of Ricardo Dos Santos
- Deposition of Edgardo Camacho
- Deposition of Suneela Mistry
- Deposition of Jeffrey Erickson
- Deposition of George Pollick
- Deposition of Robert Kaiser
- Deposition of Michael Debeau
- Deposition of Thomas C. Kupiec
- Deposition of Tommy Means
- Deposition of Samuel Penta
- Depositions of YuZon Wu
- Deposition of Lucy Wilson, M.D.
- Deposition of Joseph Alessandrini, R.Ph.
- Deposition of Mario Giamei
- Deposition of Lisa Cadden
- Deposition of Steven Higgins
- Deposition of Owen Finnegan
- Deposition of Stephen Haynes
- Deposition of Cory Fletcher
- Deposition of Annette Robinson
- Deposition of Belmira Carvalho
- BHSC Responses to Request for Production of Documents (Bates 1-1586) including, among other things, AAAHC certifications and policies and procedures
- Deposition Transcript/Exhibits of Ritu Bhambhani, MD- Box Hill Surgery Center
- Deposition Transcript/Exhibits of Andrew Vickers, RN- Box Hill Surgery Center
- Deposition of Kimberly Brockmeyer

- Deposition of Barbara Wagner
- Expert Report of David Chason, MD
- Expert Report of Lloyd Saberski, MD
- Expert Report of Shmuel Shoham, MD
- Deposition of Lloyd Saberski – Circuit Ct Baltimore County, MD-Consolidated Cases
- Deposition/Report of Lawrence Winikur
- Deposition (Rule 31) of Faye Menter- Cumberland Valley Surgery Center
- Deposition (Rule 31) of Donald Bartnick- Annapolis Surgery Center
- Deposition (Rule 31) of Susan Calhoun-Peninsula Orthopaedics
- Deposition (Rule 31) of Charlotte Rhew-James Davis (Duke) Ambulatory Surgery Center
- Deposition (Rule 31) of Diana Holt-Premier Orthopedics & Sports Medicine-TN
- Deposition (Rule 31) of Laura Ross- Adams, DO-The Ross Center
- Deposition (Rule 31) of Kimberly Mason-University of Tennessee Medical Center
- Deposition (Rule 31) of James Cathey-East Tennessee Children's Hospital
- Deposition (Rule 31) of Noli Dominguez-Central Jersey Orthopedics
- Deposition (Rule 31) of Rhonda Proscia-The Montclair Orthopaedic Group- NJ

- **Angela Farthing, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-452

- **Linda Torbeck, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-148

- **Belinda Dreisch, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center (Bates nos.:1-187)

- **Teresa Davis, Patient**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-86

- **Edna Young, Patient, Deceased Evelyn Bowman, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-82
- **John Millhausen, Patient, Deceased, Mary Joyce Armetta, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-26
- **Bahman Kashi, Patient, Deceased, Kiumarc Kashi, PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-24
- **Brenda Rozek, Patient, Deceased, Meghan Handy, Individually and as Surviving Child & PR of Estate**
Complaint
Defendants, Bhambhani & Box Hill's Answer to Complaint
Plaintiff: Certificate of Merit/Report- Lloyd Saberski, M.D.
Defendant: Certificate of Merit/Report – David Maine, M.D.
Medical Records: Dr. Ritu Bhambhani- Box Hill Surgery Center Bates nos.: 1-39